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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/562,698 Confirmation No. : 4276  
First Named Inventor : Jee Woo LEE  
Filed : December 30, 2005  
TC/A.U. : 1621  
Examiner : (To Be Assigned)  
Docket No. : 029310.57239US  
Customer No. : 23911  
Title : 4-(Methyl Sulfonyl Amino) Phenyl Analogues as Vanilloid Antagonist Showing Excellent Analgesic Activity and the Pharmaceutical Compositions Comprising the Same

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, the attached Form PTO-1449 lists documents which the Examiner may deem relevant to patentability of the claims of the above-identified application.

I. Time Period of Submission

This Information Disclosure Statement is submitted:

1) no later than three months from the application's filing date or 2) before the mailing date of the first Office Action on the merits (whichever is later) or 3) before a first Office Action after the filing of a Request for Continued Examination, and therefore no statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

2) after the later of three months from the application's filing date and the mailing date of the first Office Action on the merits, but before a Final Office Action, a Notice of Allowance, or an action closing prosecution (*Ex parte Quayle*), (whichever is earlier), and therefore Applicant is filing concurrently herewith:

- a Statement under 37 C.F.R. § 1.97(e); or
- a fee in the amount of \$180.00 under 37 C.F.R. § 1.17(p).

3) after either a Final Office Action or a Notice of Allowance, but before payment of the Issue Fee, and therefore Applicant is submitting herewith:

a Statement under 37 C.F.R. § 1.97(e); and  
a fee in the amount of \$180.00 under 37 C.F.R. § 1.17(p).

II. Statement Under 37 C.F.R. § 1.97(e)

I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or

I hereby state that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making a reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; or

III. Statement under 37 C.F.R. § 1.704(d)

I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this Information Disclosure Statement.

IV. Submission of Non-English Language Documents

The following is a concise explanation of relevance of the non-English language documents listed in the attached Form PTO-1449:

The relevance of document(s) \_\_\_\_\_ to the subject matter of the present invention is/are provided in the specification of the above-identified application.

Corresponding foreign or international report(s) citing document(s) \_\_\_\_\_, together with an English-language version(s) (if not already in English) of that portion of the report(s) indicating the degree of relevance found by the foreign office(s) is/are submitted.

English language family member publication(s) of document(s) \_\_\_\_\_ is/are noted on Form PTO-1449.

English language abstract(s) is/are submitted for document(s)

English translation(s) of the foreign language document(s)  
is/are submitted herewith.

Applicant submits the following explanations:

V. Continuations/Divisionals

Documents \_\_\_\_\_ were of record in parent application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, from which this application claims benefit. As provided in 37 C.F.R. §1.98(d), copies of the documents are not being provided since they were previously submitted to or cited by the United States Patent and Trademark Office in the afore-mentioned parent application.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

If necessary, this paper should be considered as an authorization to charge Deposit Account 05-1323, Attorney Docket No.: 029310.57239US, for the fee set forth in 37 C.F.R. § 1.17(p).

Respectfully submitted,

February 2, 2007



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Substitute for form 1449B/PTO				Complete if Known	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				Application Number	10/562,698
(use as many sheets as necessary)				Filing Date	December 30, 2005
				First Named Inventor	Jee Woo LEE
				Art Unit	1621
				Examiner Name	(To Be Assigned)
Sheet	1	of	3	Attorney Docket Number	029310.57239US

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NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.				T <sup>2</sup>
	AA	CHRISTOPHER S.J. WALPOLE et al., "Structural Requirements for Capsaicin Agonists and Antagonists", 1993, pages 63-81.				
	AB	YUN WANG et al., "High Affinity Antagonists of the Vanilloid Receptor", March 12, 2002, Vol. 62, No. 4, pages 947-956.				
	AC	GUY R. SEABROOK et al., "Functional Properties of the High-Affinity TRPV1 (VR1) Vanilloid Receptor Antagonist (4-Hydroxy-5-iodo-3-methoxyphenylacetate ester) Iodo-Resiniferatoxin", The Journal of Pharmacology and Experimental Therapeutics" 2002, Vol. 303, No. 3, pages 1052-1060.				
	AD	M.J. GUNTHORPE et al., "Identification and characterisation of SB-366791, a potent and selective vanilloid receptor (Vr1/TRPV1) antagonist", Neuropharmacology, 2004, Vol. 46, pages 133-149.				
	AE	MARTIN J. GUNTHORPE et al., "The diversity in the vanilloid (TRPV) receptor family of ion channels", TRENDS in Pharmacological Sciences, April 2002., Vol. 23, No. 4, pages 183-191.				
	AF	YUN WANG et al., "High-Affinity Partial Agonists of the Vanilloid Receptor", Molecular Pharmacology, December 24, 2002., Vol. 64, No. 2, pages 325-333.				
	AG	QUN SUN et al., "4-(2-Pyridyl)piperazine-1-carboxamides: Potent Vanilloid Receptor 1 Antagonists", Bioorganic & Medicinal Chemistry Letters, March 14, 2003, Vol. 13, pages 3611-3616.				
	AH	PETER M. ZYGMUNT et al., "Vanilloid receptors on sensory nerves mediate the vasodilator action of anandamide", Macmillan Magazines, Nature, July 29, 1999, Vol. 400, pages 452-457.				
	AI	YOUNG-GER SUH et al., "Novel Non-vanilloid VR1 Antagonist of High Analgesic Effects and Its Structural Requirement for VR1 Antagonistic Effects", Bioorganic & Medicinal Chemistry Letters, 2003, Vol. 13, pages 4389-4393.				

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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	AJ	PHILIP HAYES et al., "Cloning and functional expression of a human orthologue of rat vanilloid receptor-1", Pain, 2000, Vol. 88, pages 205-215.	
	AK	SUN WOOK HWANG et al., "Direct activation of capsaicin receptors by products of lipoxygenases: Endogenous capsaicin-Like substances", PNAS, May 23, 2000, Vol. 97, No. 11, pages 6155-6160	
	AL	ARPAD SZALLASI et al., "Vanilloid (Capsaicin) Receptors and Mechanisms", Pharmacological Reviews, Vol. 51, No. 2; pages 159-211.	
	AM	SVEN-ERIC JORDT et al., "Molecular Basis for Species-Specific Sensitivity to "Hot" Chili Peppers", Department of Cellular and Molecular Pharmacology, Univ. of California, February 8, 2002, Vol. 108, pages 421-430.	
	AN	ATTILA TÓTH et al., "Design of a High-Affinity Competitive Antagonist of the Vanilloid Receptor Selective for the Calcium Entry-Linked Receptor Population", Molecular Pharmacology, Vol. 65, No. 2, pages 282-291.	
	AO	MARK E. McDONNELL et al., "7-Hydroxynaphthalen-1-yl-urea and -amide Antagonists of Human Vanilloid Receptor 1", Bioorganic & Medicinal Chemistry Letters, 2004, Vol. 14, pages 531-534.	
	AP	GIOVANNI APPENDINO et al., "Halogenation of a capsaicin analogue leads to novel vanilloid TRPV1 receptor antagonists", British Journal of Pharmacology, 2003, Vol. 139, pages 1417-1424.	
	AQ	GIOVANNI APPENDINO et al., "Euphorbium: Modern Research on its Active Principle, Resiniferatoxin, Revives an Ancient Medicine", Life Sciences, 1997, Vol. 60, No. 10, pages 681-696.	
	AR	PHILIP WAHL et al., "Iodo-Resiniferatoxin, a New Potent Vanilloid Receptor Antagonist", Molecular Pharmacology, Vol. 59, No. 1, pages 9-15.	
	AS	CRAIG MONTELL et al., "The TRP Channels, a Remarkably Functional Family", Mini-review, Cell, March 8, 2002, Vol. 108, pages 595-598.	

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Sheet	3	of	3	Attorney Docket Number	029310.57239US

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NON PATENT LITERATURE DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
	AT	M.J. CATERINA et al., "Impaired Nociception and Pain Sensation in Mice Lacking the Capsaicin Receptor", April 14, 2000. Science, Research Articles, Vol. 288, pages 306-313.			
	AU	CHRISTOPHER S.J. WALPOLE et al., "The Discovery of Capsazepine, the First Competitive Antagonist of the Sensory Neuron Excitants Capsaicin and Resiniferatoxin", Journal of Medicinal Chemistry, 1994, Vol. 37, No. 13, pages 1942-1954.			
	AV	JAMES D. POMONIS et al., "N-(4-Tertiarybutylphenyl)-4-(3-Chlorophyridin-2-yl)tetrahydropyrazine-1(2H)-carbox-amide (BCTC), a Novel, Orally Effective Vanilloid Receptor 1 Antagonist with Analgesic Properties: II. In Vivo Characterization in Rat Models of Inflammatory and Neuropathic Pain", The Journal of Pharmacology and Experimental Therapeutics, Vol. 306, No. 1.; pages 387-393.			
	AW	NARENDER R.GAVVA et al., "Molecular Determinants of Vanilloid Sensitivity in TRPV1", The Journal of Biological Chemistry, May 7, 2004, Vol. 279, No. 19, pages 20283-20295.			
	AX	MAKOTO TOMINAGA et al., "The Cloned Capsaicin Receptor Integrates Multiple Pain-Producing Stimuli", Neuron, September 1998, Vol. 21, pages 531-543.			
	AY	MICHAEL J. CATERINA et al., "The capsaicin receptor: a heat-activated ion channel in the pain pathway", Nature, October 1997, Vol. 389, pages 816-824.			
	AZ	JEEWOO LEE et al. "N-(3-Acyloxy-2-benzylpropyl)-N-[4-(methylsulfonylamino)benzyl]thiourea Analogues: Novel Potent and High Affinity Antagonists and Partial Antagonists of the Vanilloid Receptor", Journal of Medicinal Chemistry, 2003, Vol. 46, No. 14, pages 3116-3126.			
	BA	JEEWOO LEE et al., "N-(3-Acyloxy-2-benzylpropyl)-N-(4-hydroxy-3-methoxybenzyl) thiourea Derivatives as Potent Vanilloid Receptor Agonists and Analgesics", Bioorganic & Medicinal Chemistry, 2001, Vol. 9, pages 19-32.			
	BB	KENNETH J. VALENZANO et al. "N-(4-Tertiarybutylphenyl)-4-(3-chloropyridin-2-yl)tetrahydropyrazine-1(2H)-carbox-amide (BCTC), a Novel, Orally Effective Vanilloid Receptor 1 Antagonist with Analgesic Properties: I. In Vitro Characterization and Pharmacokinetic Properties", The Journal of Pharmacology and Experimental Therapeutics, Vol. 306, No. 1, pages 377-386.			

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